

CONCLUSIONS:

The above revisions recommended by Baxter are subject to review by the Division review staff. In addition, the Chemistry staff recommends the following changes in the labeling:

1. PACKAGE INSERT

In the product name which reads "CERNEVIT™ -12 IV MULTIVITAMINS Lyophilized Sterile Powder for Reconstitution", should be revised to read

2. VIAL LABEL

a. In the product name which reads "CERNEVIT™ -12 IV MULTIVITAMINS Lyophilized Sterile Powder for Reconstitution", should be revised to read

b. Delete the line after CERNEVIT™ -12 IV MULTIVITAMINS

RECOMMENDATION:

The above changes to the labeling recommended by the Chemistry staff and any other revisions will be communicated to the Sponsor regarding the February 11, 1999 draft labeling.

/S/

Jean Temeck, M.D.
Medical Reviewer
Medical Reviewer

David Orloff, M.D.
Medical Team Leader
Chemistry Reviewer

/S/

Ron Steigerwalt, Ph.D.
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David Lewis, Ph.D.
Chemistry Reviewer

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Duu-Gong Wu
Chemistry Team Leader

/S/

/S/

Steve McCort
Project Manager

all changes acceptable
per Dr. Temeck / Orloff
(sign off on trans initial sheet
2-23-99)

ADDENDUM TO LABEL REVIEW

Application Number: 20-924

Name of Drug: Cernevit -12 IV Multivitamins

Sponsor: Baxter Healthcare

Material Reviewed: December 18, 1998, draft labeling

Submission Date(s): December 21, 1998

REVIEW:

The following additional comments, per Dr. Temeck's review (see amended comments on cover sheet for NDA 20-924) need to be conveyed to the Sponsor regarding the December 18, 1999 draft labeling :

1. Under Description section:
 - a. Paragraph 1, Line three, the phrase "single dose amber vial" should be revised to read, **DRAFT LABELING**
 - b. Under Other Ingredients section, Paragraph 1, which reads " following reconstitution with WFI," should now read **DRAFT LABELING**
DRAFT LABELING
2. Under Drug Reactions section:
 - a. This section should be titled **DRAFT LABELING** section and not Drug Reactions section.
 - B. In the second paragraph first sentence, replace **DRAFT LABELING**

/S/ [redacted] 1/29/99
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Medical Reviewer

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LABEL REVIEW

Application Number: 20-924

Name of Drug: Cernevit -12 IV Multivitamins

Sponsor: Baxter Healthcare

Material Reviewed: December 18, 1998, draft labeling

Submission Date(s): December 21, 1998

REVIEW:

The draft labeling submitted dated December 18, 1998, was sent in response to labeling recommendations FAXED to the Sponsor on December 17, 1998. All changes recommended by the Agency have been incorporated into the insert except for the following:

1. Under **Drug Reactions**, last sentence of paragraph 1, the word [REDACTED] has been replace with the symbol " α ". The revised order of drugs has been revised to read as follows:

DRAFT LABELING

2. Under **Adverse Reactions**, paragraph 1, line 2, the sentence which reads,

"There have been rare reports of anaphylactic reactions following IV injection of Cernevit™ over 1-4 minutes, one of which was fatal."

has been revised to omit the phrase [REDACTED]

The sentence now reads,

DRAFT LABELING

3. Under **Adverse Reactions**, the recommendations for paragraph 2 have not been incorporated.

Instead the following sentence has been added after paragraph 1 as follows:

DRAFT LABELING